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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/826,431	04/04/2001	Jerome J. Cuomo	5051-511	8488

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EXAMINER
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TRAN, MY CHAU T

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 07/10/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/826,431	CUOMO ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	My-Chau T. Tran	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 22 April 2002.
- 2a) This action is FINAL.                  2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-20 and 33-54 is/are pending in the application.
- 4a) Of the above claim(s) 33-43 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-20 and 44-54 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a)  The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

**DETAILED ACTION**

1. Applicant's amendment filed April 22, 2002 in Paper No. 8 is acknowledged. Claims 1-20 and 33-54 are pending. Claims 21-32 are canceled. Claims 33-43 have been withdrawn from further consideration a being drawn to a non-elected invention. Claims 44-54 are added.

*Election/Restrictions*

2. This application contains claims 33-43 drawn to an invention nonelected with traverse in Paper No. 8. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

*Claim Rejections - 35 USC § 112*

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-20 and 44-54 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a process disclosed by example 1, does not reasonably provide enablement for the scope encompassed by the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. How is the surface made and use in a detection system? Where would this surface be use in a microfluidic system? Is the surface found in the reaction vessel or the flow path? Is the surface use in preparation or

purification of viruses, enzymes, DNA, or proteins? How does it work? Is the surface part of an assay?

The enabling disclosure described by the process of example 1 in the written description is inadequate and non-enabling for the entire scope of the claims. The specification provides an enabling written description *limited to* a “substrate” produced by the process of Example 1 using the specific components of Example 1. However, it is unclear how the “passivation layer” may be related to the layers described in claim 1 and 44-50.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-20 and 44-54 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a) It is unclear what is meant by the claim 1 term “a chemically crosslinked material”.

*Given the scope encompassed by the definitions (1)-(4) it cannot be determined exactly what is included by the claim.* A “chemically crosslinked material” as defined by (1)-(4) can refer to a polymer such as polystyrene or polyethylene glycol, carbon in the form of diamond (definition (3)), RNA (definition (1)), or a polypeptide (definition (4)). Further, it is not clear what type of “chemically crosslinked material” as defined by (5) could be prepared *solely* from (a) carbon and oxygen, (b) carbon and nitrogen, or (c) carbon and hydrogen as required by definition (5).

b) The term “non-adsorption of biomolecule” of claim 1 and 44-50 is vague and indefinite. This would include bovine serum albumin that is not disclosed by the specification.

***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Thorp et al. (U.S. Patent 5,968,745).

Thorp et al. teaches a polymer-electrode (detection system) for detecting nucleic acid hybridization (Abstract; col. 3, line 9-17; fig.1), which anticipates the substrate of instant claim 1. The polymer-electrode consists of a substrate (base), a polymer membrane (coating), and an oligonucleotide probe (functional group). The features of the dependent claims are specifically described by the reference. For example, for the silicon substrate of claim 2 sees col. 5, line 10. For the electrophilic group of claim 4 sees col. 6, line 10-14. For the nucleic acid biomolecule of claim 7 see col. 4, line 48-50. For the intermediate layer of claim 19 sees fig. 1 (conductive working surface). For the indium tine oxide (ITO) of claim 20 see col. 5, line 11-16.

***Response to Arguments***

9. Applicant's arguments filed April 22, 2002 have been fully considered but they are not persuasive. The examiner's rationale is set forth below.

10. In response to applicant's argument that the term "chemically crosslinked" is well understood by those of ordinary skill in the art, it is not how those of ordinary skill in the art define the term "chemically crosslinked", but how applicant defines the term that would be unclear to those of ordinary skill in the art. Base on the claim definitions, a "chemically crosslinked material" as defined by (1)-(4) can refer to a polymer such as polystyrene or polyethylene glycol, carbon in the form of diamond (definition (3)), RNA (definition (1)), or a polypeptide (definition (4)). Further, it is not clear what type of "chemically crosslinked material" as defined by (5) could be prepared *solely* from (a) carbon and oxygen, (b) carbon and nitrogen, or (c) carbon and hydrogen as required by definition (5). Therefore from the scope encompassed by applicant's definitions of the term "chemically crosslinked", those of ordinary skill in the art would not be able to determine exactly what is included in the invention.

11. Applicants contend that there is no basis for the 35 U.S.C. 112, first paragraph, for lack of enablement. Since the specification discloses an exemplary technique for depositing a coating on a substrate and using the coating in a detection device applicants argue that it is sufficient to teach those skilled in the art how to make and use the full scope of the claimed invention.

Although the technique for depositing a coating on a substrate is known in the art, the scope of the claims encompasses such coating material as a diamond and RNA. These two types of material are very different in nature and would require undue experimentation by those

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skilled in the art in the technique for depositing a coating on a substrate. The example provide in the specification (pg. 9-10, example 1) is for a specific coating material, which is tetramethyl silane ( $\text{Si}(\text{CH}_4)_3$ ). Therefore, there is enablement in the specification for this type of coating material and not the entire scope encompassed by the claimed invention.

12. Applicant's alleges that the oligonucleotide disclosed in Thorp is not the electrophilic or nucleophilic group of the present invention. Base on the specification definition of the electrophilic groups (pg. 4, lines 26-28) and nucleophilic groups (pg. 5, lines 19-21), the scope of these definitions would include the oligonucleotide of Thorp.

### ***Conclusion***

13. No claims are allowed.

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to My-Chau T. Tran whose telephone number is 703-305-6999. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on 703-305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

mct  
July 9, 2002

*Mary E. Ceperley*  
MARY E. CEPELRY  
PRIMARY EXAMINER  
A.U.1641